## REMARKS

The Examiner has maintained the priority rejection, objected to claim 30 and presently rejects claims 1-48 based on new grounds of rejection under 35 USC § 102(e) and 35 USC § 103. The specific grounds for objection and rejection, and Applicant's response thereto, are set out in detail below.

Claim 1 and 30 have been amended and claims 1-48 are pending for reconsideration, which is respectfully requested in view of the foregoing amendments and following remarks. No new matter has been added by these amendments. Support for the amendment to claim 1 can be found in the specification at page 16, paragraphs [0048] and [0049].

### Withdrawn Rejections/Objections

The Examiner has withdrawn the rejection of claim 4 under 35 USC § 112, second paragraph, the rejection of claims 1, 3-5, 9, 11, 12, 16, 19-22, 26, 39-41 43, and 46 under 35 USC § 102(e) over US Patent No. 5,776,456, and the double patenting rejection.

### Priority Claim

The Examiner has maintained the objection to Applicant's claim of priority. The Examiner alleges that U.S. application number 09/038,955, filed on March 12, 1998 and U.S. application number 09/307,816, filed on May 10, 1999, fail to contemplate the treatment B-cell disorders (including plasma-cell disorders). In response, Applicant first notes that the instant application claims priority to U.S. Serial No. 09/307,816, which is a continuation-in-part of U.S. Serial No. 09/038,955, not vice versa, as the Examiner cites. Furthermore, the '955 application further claims priority to provisional application serial no. 60/041,506, filed March 24, 1997.

Applicant asks that the Examiner clarify the limitations that are alleged not supported by the priority documents.

### Defective Declaration

In response to the Examiner's maintained objection to the defective Declaration, Applicant submits herewith an executed, substitute Declaration with the serial number of the priority application correctly listed as 09/038,955. Applicant submits that this Declaration is

in compliance with 37 C.R.F. 1.67 (c) and withdrawal of the rejection respectfully is requested.

**Objection to Claim 30**

The Examiner has rejected claim 30 for improper dependency upon claim 29. In response, the Applicant has amended claim 30 to depend upon claim 26, as suggested by the Examiner. Accordingly, withdrawal of the objection is respectfully is requested.

**Rejections Under 35 USC § 102(e)**

The Examiner has rejected claims 1, 2, 8, 9, 11, 12, 16, 19-22, 23, 24, 26, and 44 under 35 USC § 102(e) as being anticipated by U.S. Patent No. 5,776,456 ("the '456 patent"). The Examiner has stated that the '456 patent discloses a method of treating a B cell disorder, particularly B cell lymphoma in cynomolgus monkeys. Applicant respectfully traverses.

In order to reject a claim under 35 USC § 102, the Examiner must demonstrate that each and every claim element is contained in a single prior art reference. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *see also* MPEP § 2131 (August 2001). Applicant submits that the '456 patent cited by the Examiner does not anticipate the claims because it does not teach every element of the claims. The instant claims are directed to the treatment of a horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat. The '456 patent fails to describe any method of treating horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat. Further, the instant application claims a method for treating a T-cell, myeloid-cell, mast-cell, or plasma-cell disorders. The '456 patent fails to describe any method of treating T-cell, myeloid-cell, mast-cell, or plasma-cell disorders. As such, the '456 patent cannot anticipate the claimed invention, and withdrawal of the rejection respectfully is requested.

**Rejections Under 35 USC § 103(a)**

***The '456 patent in view of the '242 patent and Rybak et al.***

The Examiner has rejected claims 1-5, 7-9, 11, 12, 15-29, 32-35, and 37-46 under 35 USC § 103(a) as being unpatentable over Anderson *et al.* (U.S. Patent No. 5,776,456 - "the '456 patent") in view of Holliger *et al.* (U.S. Patent No. 5,837,242 - "the '242 patent") and Rybak *et al.*

The Examiner alleges that: (1) the '456 patent "teaches the administration to human patients of therapeutic compositions comprising radiolabeled chimeric antibodies, wherein the radioisotope is yttrium 90 or radionuclide indium 111; [and] the combination of antibodies", (2) "Rybak teaches the use of chimeric antibodies linked to toxins such as RNase to target tumor cells", and (3) the '242 patent "teaches the use of bispecific antibodies in the recruitment of powerful effector functions of cytotoxic T cells or natural killer (NK) cells, as well as a tool for imaging". Based on these allegations, the Examiner asserts that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to utilize the different combinations of the therapeutic compositions as anti-cancer medicaments for any primate, and suggests that the skilled artisan would have been motivated to manufacture such a medicament. Applicant respectfully traverses these rejections.

All claims are presumed initially to be non-obvious. A *prima facie* case of obviousness requires three elements: (1) a teaching or suggestion of all of the claim limitations; (2) a suggestion or motivation to modify or combine the teachings of the applied prior art; and (3) a reasonable expectation of success in reaching the claimed invention. The Examiner bears the initial burden of supporting any *prima facie* assertion of obviousness with adequate facts. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). See MPEP § 2142. The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the reference must expressly or impliedly suggest the claimed invention, or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Applicant submits that the Examiner's comments regarding the cited references fail to meet this test. As such, Applicant respectfully submits that the rejection should be withdrawn.

The instant claims are directed to the treatment of a B-cell, T-cell, myeloid-cell, mast-cell, or plasma-cell disorder in a horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat. The '456 patent fails to describe any method of treating T-cell, myeloid-cell, mast-cell, or plasma-cell disorders. The '456 patent fails to suggest or describe any method of treating horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat. Applicant submits that Rybak *et al.* and the '242 patent fail to provide a teaching or suggestion of these missing claim limitations.

The Examiner's suggestion that the use of cynomlogous monkeys in the '456 patent would have provided motivation to the skilled artisan is incorrect. One of skill in the art reading the '456 patent, as a whole, would not be motivated to extend the teaching of the '456 patent to the treatment of a horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat. More particularly, the Examiner's reliance on Rybak *et al.* and the '242 patent to advance this motivation is misplaced. The Examiner has alleged that Rybak *et al.* teach the use of chimeric antibodies linked to toxins such as RNase to target tumor cells, and the '242 patent allegedly teaches the use of bispecific antibodies in the recruitment of powerful effector functions of cytotoxic T cells or natural killer (NK) cells, as well as an imaging tool. These teachings are irrelevant to the alleged motivation.

Because the combination of cited prior art does not teach or suggest the of all these missing claim limitations and fails to provide the requisite motivation, the Examiner has failed to demonstrate the first two elements of a *prima facie* case of obviousness. As such, withdrawal of the rejection respectfully is requested.

***The '456 patent in view of the '869 patent***

This rejection relies on the same teaching of the '456 patent as described above, and therefore accordingly fails for the same reasons. The Examiner has alleged that the '869 patent teaches diagnostic or therapeutic agents including radionuclides, drugs, anti-tumor agents, toxins, etc., as well as the use of haptens for the treatment of cancer and autoimmune diseases.

The Examiner has alleged that it would have been *prima facie* obvious to one of ordinary skill in the art to utilize different combinations of the therapeutic compositions for an autoimmune disease, as well as cancer for any primate animal and that one of ordinary skill in the art would have been motivated to manufacture such a medicament in order to treat non-human primates as a monkey companion animal, as well as other domestic or companion animals because the patent sets forth that the disclosed treatment of B cell lymphomas targeting the CD20 antigen is not limited to non-human primates.

The '456 patent fails to suggest or describe any method of treating horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat, and the '869 patent fails to provide the a teaching or suggestion of these missing claim limitations. Nowhere in the '869 patent is the teaching or suggestion to treat animals selected from the group consisting of horse, cattle, sheep, goat, llama,

alpaca, pig, dog, or cat. Accordingly, Applicant respectfully submits that the rejection is improper and should be withdrawn.

***The '456 patent in view of Javid et al.***

This rejection relies on the same teaching of the '456 patent as described above, and re-iterates that the '456 patent "does not teach a method for treating a B-cell or plasma disorder in a domestic animal, such as a dog, cat or horse . . . " The Examiner asserts that Javid *et al.* "teaches that neutron-capturing isotopes such as boron 10 can be administered for the treatment of neoplasms. Applicant points out that nowhere in Javid is there the teaching or suggestion to treat a B-cell, T-cell, myeloid-cell, mast-cell, or plasma-cell disorder in a horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat, by administering a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody component that is specific to a B-cell, T-cell, myeloid, mast cell, or plasma cell antigen or epitope in the horse, cattle, sheep, goat, llama, alpaca, pig, dog, or cat. As such, withdrawal of the rejection respectfully is requested.

## CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that claims 1 to 48 are in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

Respectfully submitted,

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